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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,743	07/03/2001	Krassen Dimitrov	P-IS 4548	3666

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

12

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/898,743

Applicant(s)

DIMITROV, KRASSEN

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) 16-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 78-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action (Paper No. 10) filed on April 11, 2003 has been entered.
2. The Information Disclosure Statement (Paper No. 11) filed on April 17, 2003 has been entered and considered.

Response to Arguments

3. Applicant's response to the office action (Paper No.10) is fully considered and deemed persuasive in part.
4. With reference to the rejection made in the previous office action under 35 USC 112, second paragraph, Applicants' arguments are fully considered and the rejection is withdrawn in view of the arguments (Paper NO. 10).
5. The following is the rejection made in the previous office action under 35 U.S.C. 102(b):

A. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chandler (WO 99/52708).

Chandler teaches microparticles with multiple fluorescent signals wherein Chandler et al. disclose (i) a unique or distinct population of labels comprising one or more unique labels bound to DNA (microparticles) (see page 5, lines 28-34, page 6, lines 23-33, see page 8, lines 19-22); (ii) unique labels or dyes comprise unique emission spectra (see page 6, lines 2-4) which is unique to the specific set or population (see page 23, lines 17-25); (iii) unique labels comprise mixture of two or more (64 - 40,960) different or distinctly labeled particles created through variation of the amount of or type of dye (see page 17, lines 28-37, page 18, lines 1-15, page 6, lines 23-33); (iv) labels comprise fluorescent dyes (see page 15, lines 28-32). Thus the disclosure of Chandler meets the limitations in the instant claims.

Response to arguments:

Applicants' arguments with reference to the rejection under 35 USC 102(b) as being anticipated by Chandler have been fully considered and found not persuasive. Applicants argue

Art Unit: 1637

that Chandler does not teach label monomer such as fluorescent dye molecule attached or bound to a nucleotide in a 1:1 correspondence as recited in the specification. This argument is fully considered. However, as stated in MPEP 2145, "Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims". In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993), the instant claims do not recite this limitation and specification is not be read into the claims. Further there is no requirement that the converse of the claims occurs, that is, that each nucleic acid molecule is bound to a label, only that each label is bound to a nucleic acid molecule. Separately "about" 80 can read on a single label bound to a single nucleic acid molecule given the broad reading of applicants' arguments. Thus the disclosure of Chandler meets the limitations in the instant claims and therefore the rejection is maintained.

6. With reference to the rejection made in the previous office action under 35 USC 102 (e), Applicants arguments are fully considered and the rejection is withdrawn in view of the arguments (Paper No. 10)

7. The following is the rejection made in the previous office action under 35 USC 103(a):

Claims 7-15 and 78-84 rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (WO 99/52708) and in view of Chandler et al. (WO 99/37814).

Chandler teaches microparticles with multiple fluorescent signals wherein Chandler et al. disclose (i) a unique or distinct population of labels comprising one or more unique labels bound to DNA (microparticles) (see page 5, lines 28-34, page 6, lines 23-33, see page 8, lines 19-22); (ii) unique labels or dyes comprise unique emission spectra (see page 6, lines 2-4) which is unique to the specific set or population (see page 23, lines 17-25); (iii) unique labels comprise mixture of two or more (64 - 40,960) different or distinctly labeled particles created through variation of the amount of or type of dye (see page 17, lines 28-37, page 18, lines 1-15, page 6, lines 23-33); (iv) labels comprise fluorescent dyes (see page 15, lines 28-32). However Chandler did not teach labeled probes attached to unique labeled microparticle.

Art Unit: 1637

Chandler et al. ('814) teach microparticles attached with oligonucleotide probes wherein Chandler et al. disclose (v) uniquely labeled probes (fluorescent probes) comprising 20-50 fold concentration of target specific probes bound to the beads (see page 28, lines 20-33, page 29, lines 20-23);(vi) diverse population of uniquely labeled probes comprise two attached populations of nucleic acids, which include fluorescent probes and oligonucleotide bound to the bead (see page 29, lines 20-23); (vii) a kit comprising a series unique set of fluorescent labels bound to a nucleic acid (genedigit) an a fluorescent probe (anti-genedigit), competitor molecule (specifier), a reference material (genedigit) (see page 6, lines 23-30).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine the labeled microparticles as taught by Chandler with the labeled probes as taught by '814 to achieve expected advantage of developing an efficient population of unique labeled probes because '814 suggests that "the fluorescent particles can be used for passive or covalent coupling of biological material such as haptens, enzymes or nucleic acids and used for various types of analyte assays applicable to medical, diagnostic and industrial applications." (see page 17, lines 31-33, page 18, lines 1-2). An ordinary practitioner would have been motivated to combine the teachings of Chandler with the teachings of Chandler et al. to achieve wide use of the uniquely labeled particles by incorporating the labeled probes because these limitations would improve the applicability of the unique labels in medical, diagnostic and industrial applications.

Response to arguments:

Applicants' arguments are fully considered and found not persuasive. Applicants' argue that the term bound is taught in the instant specification and that a label monomer attached to a nucleotide in a 1:1 correspondence is taught neither by Candler nor Chandler et al. This argument is fully considered and as discussed above the limitation is not found in the instant claims and the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992). An ordinary practitioner is motivated to combine the teachings of Chandler with that of Chandler et al. to develop a diverse population of uniquely labeled probes and nucleic acid

labeling kit comprising the labeled probes. Therefore, the rejection is maintained herein.

New grounds of rejections

8. Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Dattagupta et al. (USPN. 4,824,775).

Dattagupta et al. teach with multiple fluorescent signals bound to a nucleic acid (DNA, RNA, or oligonucleotide) wherein Dattagupta et al. disclose (i) a unique or diverse population of labels comprising multiple unique labels bound to DNA (see column 3, lines 4-16, column 2, lines 14); (ii) unique labels or dyes comprise unique emission spectra which is unique to the specific set or population (see column 2, lines 1-18, column 8, lines 1-11); (iii) unique labels comprise mixture of 20, 100, or 5,000 different or distinctly labels created through variation of the amount of or type of dye (column 3, lines 22-23, column 4, lines 3-11, column 1, lines 35-36); (iv) labels comprise fluorescent dyes (see column 3, lines 22-23). Thus the disclosure of Dattagupta et al. meets the limitations in the instant claims.

Conclusion

No claims are allowable.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on April 17, 2003 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.


If attempts to reach the examiners by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Application/Control Number: 09/898,743

Page 7

Art Unit: 1637

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
June 26, 2003


JEFFREY FREDMAN
PRIMARY EXAMINER